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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/617,923	07/17/2000	Laurie H. Glimcher	HUI-026DV2	8932

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EXAMINER
GAMBEL, PHILLIP

ART UNIT	PAPER NUMBER
1644	10

DATE MAILED: 06/24/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/617923	GLIM CHEN	
	Examiner	Art Unit	
	GAMBEL	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☑ Responsive to communication(s) filed on 3/12/01

2a)☑ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☑ Claim(s) _____ is/are pending in the application. 33-35, 46-56

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☑ Claim(s) _____ is/are rejected. 33-35, 46-56

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☑ The drawing(s) filed on 7/7/00 is/are: a)☐ accepted or b)☑ objected to by the Examiner. See Previous PTO948

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☑ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

1. Applicant's amendment, filed 3/12/02 (Paper No. 9), has been entered.
Claims 36 and 45 have been canceled. Claims 1-32 and 37-44 have been canceled previously.
Claims 33 and 35 have been amended.
Claims 46-56 have been added.

Claims 33-35 and 46-56 are pending and being acted upon presently.

2. The text of those sections of Title 35 USC not included in this Action can be found in a prior Action.
This Office Action will be in response to applicant's arguments, filed 3/12/02 (Paper No. 9).
The rejections of record can be found in the previous Office Action (Paper No. 7).

3. Formal drawings and photographs have been submitted which fail to comply with 37 CFR 1.84.
Please see the form PTO-948 previously sent in Paper No. 7.

INFORMATION ON HOW TO EFFECT DRAWING CHANGES

A. Correction of Informalities -- 37 CFR 1.85

New corrected drawings must be filed with the changes incorporated therein. Identifying indicia, if provided, should include the title of the invention, inventor's name, and application number, or docket number (if any) if an application number has not been assigned to the application. If this information is provided, it must be placed on the front of each sheet and centered within the top margin. If corrected drawings are required in a Notice of Allowability (PTOL-37), the new drawings MUST be filed within the THREE MONTH shortened statutory period set for reply in the "Notice of Allowability." Extensions of time may NOT be obtained under the provisions of 37 CFR 1.136 for filing the corrected drawings after the mailing of a Notice of Allowability. The drawings should be filed as a separate paper with a transmittal letter addressed to the Official Draftsperson.

B. Corrections other than Informalities Noted by Draftsperson on form PTO-948.

All changes to the drawings, other than informalities noted by the Draftsperson, MUST be made in the same manner as above except that, normally, a highlighted (preferably red ink) sketch of the changes to be incorporated into the new drawings MUST be approved by the examiner before the application will be allowed. No changes will be permitted to be made, other than correction of informalities, unless the examiner has approved the proposed changes.

Timing of Corrections

Applicant is required to submit acceptable corrected drawings within the time period set in the Office action. See 37 CFR 1.185(a). Failure to take corrective action within the set (or extended) period will result in ABANDONMENT of the application.

4. Claims 33-35 and 46-56 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection

The specification does not provide adequate written description of the claimed invention, namely, "portion thereof", "at least 60% / 70%/ 80% / 90% / 95% homologous to the sequence set forth in SEQ ID NO: 2", "comprising at least 8 / 10 / 15 / 20 / 30 amino acid residues of the amino acid sequence set forth in SEQ ID NO: 2" other than that set forth in SEQ ID NO: 2 or encoded by SEQ ID NO: 1, as disclosed in the instant specification as-filed because the relevant identifying characteristics such as structure or other physical and/or chemical characteristics are not set forth in the specification as-filed.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention.* The invention is, for purposes of the 'written description' inquiry, whatever is now claimed." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.)

Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993) and Amgen Inc. V. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016.

One cannot describe what one has not conceived. See Fiddes v. Baird, 30 USPQ2d 1481, 1483. In Fiddes v. Baird, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class. The specification provided only the bovine sequence. Thus, the specification fails to describe these DNA sequences. The Court further elaborated that generic statements are not an adequate written description of the genus because it does not distinguish the claimed genus from others, except by function.

Finally, the Court indicated that while applicants are not required to disclose every species encompassed within a genus, the description of a genus is achieved by the recitation of a representative number of DNA molecules, defined by nucleotide sequence, falling within the scope of the genus, See The Regents of the University of California v. Eli Lilly and Company, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997).

Applicant is claiming a generic class of molecules, namely polypeptides or proteins or portions thereof related to NIP45 set forth in SEQ ID NO: 2 or portions thereof, including comprising peptides thereof as the targeted specificity of the claimed antibodies based upon the support of the disclosure of a limited representative number of species, encoded by SEQ ID NO: 1 or set forth in SEQ ID NO: 2 / NIP45. The instant invention encompasses any polypeptide or protein that is related to SEQ ID NO: 2 / NIP45 via homology or partial sequence, yet the instant specification does not provide sufficient written description as to the critical or identifying structural features of said SEQ ID NO: 2 / NIP45 proteins and the correlation between the chemical structure and the desired structural and/or function. The reliance on the disclosed limited example of a particular SEQ ID NO: 2 / NIP45 protein specificity does not support the written description of any polypeptide or protein related to SEQ ID NO: 2 / NIP45.

It has been well known that minor structural differences even among structurally related compounds or compositions can result in substantially different biological or pharmacological activities.

Mere idea or function is insufficient for written description; isolation and characterization at a minimum are required

Skolnick et al. (Trends in Biotech., 18(1):34-39, 2000) disclose that the skilled artisan is well aware that assigning functional activities for any particular protein or protein family based upon sequence homology is inaccurate, in part because of the multifunctional nature of proteins (e.g., "Abstract" and "Sequence-based approaches to function prediction", page 34). Even in situations where there is some confidence of a similar overall structure between two proteins, only experimental research can confirm the artisan's best guess as to the function of the structurally related protein (see in particular "Abstract" and Box 2). Thus an assignment of function based upon sequence homology or identity without further functional analysis does not appear to provide sufficient written support for the claimed NIP45 specificity, other than that disclosed in the specification as-filed.

The instant claims do not provide sufficient functional characteristics coupled with a known or disclosed correlation between function and structure. Since the disclosure fails to describe the common attributes or characteristics that identify members of the genus, and because the genus can be highly variable, the disclosure of SEQ ID NOS: 1 and 2 are insufficient to describe the genus of any SEQ ID NO: 2 / NIP45 related polypeptide or protein or portion thereof, encompassed by the claimed antibody specificities.

The genus encompasses antibodies that can bind SEQ ID NO: 2 / NIP45 related polypeptides, proteins or portions thereof wherein such SEQ ID NO: 2 / NIP45 - related proteins or portions thereof could encompass have numerous differences in amino acid sequences, including numerous differences in linear and conformational epitopes.

However, the present specification fails to provide sufficient disclosure of such SEQ ID NO: 2 / NIP45 related proteins and portions thereof that maintain the structural and functional properties of the SEQ ID NO: 2 / NIP45 or portions thereof encompassed by SEQ ID NOS: 1 and 2. The specification does not provide sufficient guidance as to which of the amino acids may be changed while SEQ ID NO: 2 / NIP45 structural or functional activity and specificity is retained, nor the written description of these homologous polypeptides, proteins or portions thereof.

For example, Lederman et al. (Molecular Immunology 28: 1171-1181, 1991) disclose that a single amino acid substitution in a common allele ablates binding of a monoclonal antibody (see entire document).

For example, Li et al. (PNAS 77: 3211-3214, 1980) disclose that dissociation of immunoreactivity from other biological activities when constructing analogs (see entire document

Here, there is insufficient written description of the numerous polypeptides, proteins, and portions thereof encompassed by the claimed invention wherein a single amino acid can result in profound differences in antibody specificity and other biological activities.

Also, given the broad range of polypeptides, proteins and portions thereof encompassed by the claimed invention, these polypeptides, proteins and portions thereof would likely comprise cross-reactive epitopes with other molecules that do not relate to SEQ ID NO: 2 / NIP 45.

The Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement make clear that if a claimed genus does not show actual reduction to practice for a representative number of species; then the Requirement may be alternatively met by reduction to drawings, or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the genus (Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001, see especially page 1106 column 3).

In the absence of structural characteristics that are shared by members of the genus of SEQ ID NO: 2 / NIP45 related proteins , one of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe the genus. Thus, applicant was not in possession of the claimed genus. See University of California v. Eli Lilly and Co. 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997).

With the exception of SEQ ID NOS: 1 and 2 disclosed in the specification as filed; the skilled artisan could not envision the detailed chemical structure encompassed by the claimed any SEQ ID NO: 2 / NIP45 related protein, polypeptide or portion thereof that the target of the claimed specific antibodies at the time the invention was made and based upon the specification as filed. Applicant has failed to provide sufficient written description for all of the "SEQ ID NO: 2 / NIP45 related protein, polypeptide or portion " specifically bound by the claimed antibodies.

Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 USC 112 is severable from its enablement provision. (See page 1115.)

Applicant is directed to the Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

5. Claims 33-35 and 46-56 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for "NIP45 protein" set forth in SEQ ID NO: 2 or encoded by SEQ ID NO: 1, does not reasonably provide enablement for any SEQ ID NO: 2 / NIP45 related polypeptide, protein or "portion thereof", "at least 60% / 70%/ 80% / 90% / 95% homologous to the sequence set forth in SEQ ID NO: 2", "comprising at least 8 / 10 / 15 / 20 / 30 amino acid residues of the amino acid sequence set forth in SEQ ID NO: 2" as encompassed by the claimed antibody specificities. The specification does not enable any person skilled in the art to which it pertains, or with which it is most clearly connected, to make and use the invention commensurate in scope with these claims.

Applicant has not provided sufficient biochemical information (e.g. molecular weight, amino acid composition, N-terminal sequence, etc.) that distinctly identifies SEQ ID NO: 2 / NIP45 related polypeptide, protein or "portion thereof", "at least 60% / 70%/ 80% / 90% / 95% homologous to the sequence set forth in SEQ ID NO: 2", "comprising at least 8 / 10 / 15 / 20 / 30 amino acid residues of the amino acid sequence set forth in SEQ ID NO: 2" as encompassed by the claimed antibody specificities other than those encompassed by SEQ ID NOS. 1 and 2 .

While the SEQ ID NO: 2 / NIP45 related polypeptides, proteins and portions thereof may include the ability of the protein to interact with Rel Homology domain of an NFAT family protein, there is insufficient guidance and direction to predicting that the scope of antibodies would maintain the specificity for SEQ ID NO: 2/ NIP45 protein. The specification does not describe nor enable any NIP45 protein other than those defined by SEQ ID NOS. 1 and 2.

The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims.

Factors to be considered in determining whether undue experimentation is required are summarized in In re Wands, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988). The factors most relevant to this rejection are the scope of the claim, unpredictability in the art, the amount of experimentation required, and the amount of direction or guidance presented.

The specification disclosure is insufficient to enable one skilled in the art to practice the invention as broadly claimed without an undue amount of experimentation. Besides the SEQ ID NO: 2 / NIP45 related polypeptides, proteins and portions thereof defined by SEQ ID NO: 2, the specification fails to provide sufficient guidance and direction as to how to make or use the claimed antibodies that bind said related polypeptides, proteins and portions thereof, broadly encompassed by the claimed invention.

A person of skill in the art is not enabled to make and use SEQ ID NO: 2 / NIP45 related polypeptides, proteins, and portions thereof as antibody specificities, as broadly encompassed by the claimed invention. A person of skill in the art would not know which sequences are essential, which sequences are non-essential, and what particular sequence lengths identify essential sequences. There is insufficient guidance based on the disclosure of the instant specification to direct a person of skill in the art to select or to predict particular sequences as essential for in defining the structural and functional characteristics of a SEQ ID NO: 2 /NIP45 related polypeptide, protein or portion thereof and, in turn, defining antibodies that are specific for said SEQ ID NO: 2 / NIP45.

Skolnick et al. (Trends in Biotech., 18(1):34-39, 2000) disclose that the skilled artisan is well aware that assigning functional activities for any particular protein or protein family based upon sequence homology is inaccurate, in part because of the multifunctional nature of proteins (e.g., "Abstract" and "Sequence-based approaches to function prediction", page 34). Even in situations where there is some confidence of a similar overall structure between two proteins, only experimental research can confirm the artisan's best guess as to the function of the structurally related protein (see in particular "Abstract" and Box 2). Thus an assignment of function based upon sequence homology or identity without further functional analysis does not appear to provide sufficient enabling support for the claimed SEQ ID NO: 2 / NIP45 related polypeptide, protein or portion thereof and so the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue.

A person of skill in the art is not enabled to make and use SEQ ID NO:2 / NIP45 related polypeptide, protein or portion thereof as broadly encompassed by the claimed invention. A person of skill in the art would not know which sequences are essential, which sequences are non-essential, and what particular sequence lengths identify essential sequences. There is insufficient guidance based on the disclosure of the instant specification to direct a person of skill in the art to select or to predict particular sequences as essential for in defining the structural and functional characteristics of a SEQ ID NO: 2 / NIP45 related polypeptide, protein or portion thereof and, in turn, defining antibodies that are specific for said SEQ ID NO: 2 / NIP45.

Since the amino acid sequence of a polypeptide determines its structural and functional properties, predictability of which changes can be tolerated in a polypeptide's amino acid sequence and still retain similar functionality requires a knowledge of and guidance with regard to which amino acids in the polypeptide's sequence, if any, are tolerant of modification and which are conserved (i.e. expectedly intolerant to modification), and detailed knowledge of the ways in which a polypeptide's structure relates to its functional usefulness. However, the problem of predicting polypeptide structure from mere sequence data of a single amino acid sequence and in turn utilizing predicted structural determinations to ascertain binding or functional aspects of SEQ ID NO: 2 / NIP45 related polypeptides, proteins or portions thereof and finally what changes can be tolerated with respect thereto is complex and well outside the realm of routine experimentation.

In re Fisher, 166 USPQ 18 indicates that the more unpredictable an area is, the more specific enablement is necessary in order to satisfy the statute.

It has been well known to those skilled in the art at the time the invention was made that minor structural differences among structurally related compounds or compositions can result in substantially different biological and pharmacological activities.

Because of the lack of sufficient guidance and predictability in determining which modifications would lead to defining the structural and functional characteristics of SEQ ID NO: 2 / NIP45 related polypeptides, proteins and portions thereof and that the relationship between the sequence of a peptide and its tertiary structure (i.e. its activity) was not well understood and was not predictable (e.g. see Ngo et al., in The Protein Folding Problem and Tertiary Structure Prediction, 1994, Merz et al., (ed.), Birkhauser, Boston, MA, pp. 433 and 492-495.); it would require an undue amount of experimentation for one of skill in the art to arrive at the breadth of SEQ ID NO: 2 / NIP45 related polypeptides, proteins and portions thereof and, in turn, antibodies specific thereto.

The genus encompasses antibodies that can bind SEQ ID NO: 2 / NIP45 wherein such SEQ ID NO: 2 / NIP45 related polypeptides, proteins and portions thereof could encompass have numerous differences in amino acid sequences, including numerous differences in linear and conformational epitopes.

However, the present specification fails to provide sufficient disclosure of such SEQ ID NO: 2 / NIP45 related polypeptides, proteins or portions thereof that maintain the structural and functional properties of the NIP45 protein encompassed by SEQ ID NO: 2. The specification does not provide sufficient guidance as to which of the amino acids may be changed while SEQ ID NO: 2 / NIP45 structural or functional activity and specificity is retained.

For example, Lederman et al. (Molecular Immunology 28: 1171-1181, 1991) disclose that a single amino acid substitution in a common allele ablates binding of a monoclonal antibody (see entire document).

For example, Li et al. (PNAS 77: 3211-3214, 1980) disclose that dissociation of immunoreactivity from other biological activities when constructing analogs (see entire document).

Here, there is insufficient enablement of the numerous polypeptides, proteins, and portions thereof encompassed by the claimed invention wherein a single amino acid can result in profound differences in antibody specificity and other biological activities, wherein the claimed antibody specificities still bind SEQ ID NO: 2 / NIP45.

Also, given the broad range of polypeptides, proteins and portions thereof encompassed by the claimed invention, these polypeptides, proteins and portions thereof would likely comprise cross-reactive epitopes with other molecules that do not relate to SEQ ID NO: 2 / NIP 45.

In view of the quantity of experimentation necessary, the limited working examples, the unpredictability of the art, the lack of sufficient guidance in the specification and the breadth of the claims, it would take undue trials and errors to practice the claimed invention.

6. Applicant's arguments, filed 3/12/02 (Paper No. 9), have been fully considered but are not found convincing essentially for the reasons of record and set forth herein as they relate to the newly amended and added claimed limitations.

Applicant argues the amended claims have obviated the previous rejection under 35 USC 112, first paragraph, written description.

Further, applicant argues that NIP45 protein is sufficiently described in the specification to enable the ordinary skilled artisan to produce antibodies that specifically bind NIP 45 protein.

Applicant relies upon isolating and identifying other mammalian NIP45 homologs by using standard hybridization techniques.

Also, applicant relies upon the functional characteristics that correlate to the structural characteristics of NIP45 proteins, including synergy with NP-AT to stimulate transcription from promoter containing NF-AT binding sites and c-Maf to stimulate transcription from the IL4-promoter as well as detecting NIP45 proteins through standard in vitro interaction assays using GST-NF-AT RHD fusion protein.

Applicant submit that based on the disclosed structural and functional features of NIP45 proteins , the correlation between the structural and functional features of the NIP45 proteins and the art-recognized methods of producing and detecting NIP45 proteins, it would have been routine for the for the ordinary artisan to produce homologs of the disclosed NIP45 proteins.

Here, there is insufficient written description and enablement of the numerous polypeptides, proteins, and portions thereof encompassed by the claimed invention wherein a single amino acid can result in profound differences in antibody specificity and other biological activities, wherein the claimed antibody specificities still bind SEQ ID NO: 2 / NIP45.

Also, given the broad range of polypeptides, proteins and portions thereof encompassed by the claimed invention, these polypeptides, proteins and portions thereof would likely comprise cross-reactive epitopes with other molecules that do not relate to SEQ ID NO: 2 / NIP 45, including those having the structural and functional features of SEQ ID NO: 2 / NIP 45.

The present specification fails to provide sufficient disclosure of the claimed SEQ ID NO: 2 / NIP45 related polypeptides, proteins or portions thereof that maintain the structural and functional properties of the NIP45 protein encompassed by SEQ ID NO: 2.

Applicant's arguments are not found persuasive for the reasons set forth herein and of record.

7. Applicant's cancellation of claim 36 in Paper No. 9, filed 3/12/02, has obviated the previous rejection under 35 U.S.C. 112, first paragraph, enablement.

8. Claim 35 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 35 lacks proper antecedent basis to the antibody of claim 34, given that the claim 35 is conjugated or labeled antibody and claim 33 is not a conjugated or labeled antibody.

Applicant's submission, filed 3/12/02 (Paper No. 9), that amending the claim to recite "wherein the antibody is further" is acknowledged. However, applicant is invited to amend claim 35 to recite the coupled or conjugated antibody in the preamble for proper antecedent basis.

Applicant is invited to submit claim 35 with the appropriate preamble or recitation to obviate this rejection.

Applicant should specifically point out the support for any amendments made to the disclosure. See MPEP 714.02 and 2163.06

9. No claim is allowed.

The instant NIP45-specific antibodies, wherein NIP45 is set forth in SEQ ID NOS: 1 and 2 appears free of the prior art.

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phillip Gambel whose telephone number is (703) 308-3997. The examiner can normally be reached Monday through Thursday from 7:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Phillip Gambel, PhD.
Primary Examiner
Technology Center 1600
June 27, 2002